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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/586,932 | 07/21/2006 | Else Marie Celine Defoor | 10556.204-US | 1922 |

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| EXAMINER |
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DUFFY, PATRICIA ANN

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| ART UNIT | PAPER NUMBER |
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1645

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04/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/586,932 | Applicant(s) DEFOOR ET AL. | |
| | Examiner Patricia A. Duffy | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 37-60 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7-21-06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-21-06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment</u> . |

DETAILED ACTION

The preliminary amendment to the claims filed 7-21-06 has been entered into the record. Claims 37-60 are pending and under examination.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

The information disclosure statement filed 7-21-06 has been considered. An initialed copy is enclosed.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to nucleic acids/vectors/host cells comprising nucleic acid variants up to "at least 60%" identical to a gene encoding an orotate transporter polypeptide comprising an amino acid sequence at least 60% identical to SEQ ID NO:2. Applicants call the nucleic acid encoding the orotate transporter *ysbC*. *ysbC* is characterized in the specification at page 1, "A search in the public databases for any polypeptide having amino acid homology to the orotate transporter of the present invention, revealed that the closest polypeptide had less than 35% sequence identity, and it was completely unrelated to the orotate transporter of the present invention. Consequently, the *ysbC*-encoded orotate transporter represents a **completely pioneering new class of molecules** [emphasis added]. The claims encompass a vast array of nucleic acid and protein variants from a wide variety of different organisms (see pages 11-15 of

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the specification) which is described as pioneering in nature. As such, the art does not recognize a correlation of the structure of the protein with the function of "orotate transport". The specification discloses a single nucleic acid encoding a *Lactococcus lactis* nucleic acid sequence comprising the nucleic acid sequence set forth in SEQ ID NO:1 that encodes an orotate transporter as set forth by the amino acid sequence of SEQ ID NO:2. The specification does not set forth a representative number of species to allow the skilled artisan to envision which parts of the structure are essential for function as an orotate transporter. None of these variant sequences meets the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The specification only discloses a polynucleotide sequence consisting of SEQ ID NO: 1 which corresponds to the polynucleic acid sequence encoding the, for the reasons set forth below. The actual structure or other relevant identifying characteristics of each nucleic acid that encodes a variant protein having the claimed properties of an orotate transporter protein can only be determined empirically by actually making every nucleic acid that encodes the recited variability (i.e. the instant percent identity) and testing each to determine whether it encodes a protein having the particularly disclosed properties of an *ysbC* encoded transporter protein. There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function.

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Applicants specification proposes the converse, yet still does not meet the requirements for an adequate written description of the claimed invention. Applicants propose that the skilled artisan is to modify a known nucleic acid sequence encoding a known protein sequence and that modification would still describe applicants invention as a ysbC protein as disclosed. The ysbC transporter polypeptide is member of a pioneering new claims of molecules and has specific biological properties dictated by the structure of the protein and the corresponding structure of the structural gene sequence which encodes it. There must be some nexus between the structure of a gene sequence, the structure of the protein encoded, and the function of that encoded protein. However, function can not be predicted from the modification of the structure of the gene or in this case the gene encoding the protein. Applicants have not shown that, by modifying a reference sequence encoding a reference polypeptide as claimed, will automatically predict the production of a orotate transport protein as disclosed. While it is true that, due to the nature of codon degeneracy, applicant may take a reference sequence and modify that sequence to be a different nucleic acid sequence, yet still have that nucleic acid encode the same ysbC protein. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotides encoding a representative number ysbC encoding transport polypeptides or nucleic acids encoding such, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Although the specification teaches that variants can be readily screened, the specification and the claim do not provide any guidance on the structure of the polypeptide and what changes can or can not be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. Since the disclosure fails to describe the common attributes or structural characteristics that identify members of the genus, and because the genus is highly variant, the function of orotate transport in the "pioneering new class of molecules" and there is no art established correlation of structure with function the single species alone is insufficient to describe the claimed genus of orotate transport polypeptides of that function equivalently. One of skill in the art would reasonably conclude that the disclosure of a single SEQ ID NO:1, fails to provide a representative number of species of nucleic acids encoding orotate transport polypeptides to describe the claimed genus. Mere function does not describe a structure, because the specification does not provide relevant identifying characteristics, including functional characteristics when coupled with known or disclosed correlation between function and structure. The courts have held that in these instances, the specification lacks written description see *Enzo Biochem Inc. v. Gen-Probe Inc.* 63 USPQ2D 1609 (CAFC 2002) and *University of Rochester v. G.D. Searle & Co.* 69 USPQ2D 1886 (CAFC 2004). Furthermore, a method of obtaining such sequences is not found to be a description of the nucleic acid or protein sequences per se. When the genus is vast and compounds are claimed by function and the specification and the art lacks a known or disclosed correlation between structure and function, the written description of a single nucleic acid encoding a single polypeptide as set forth in the specification does not convey possession of the claimed genus. Applicants were not in possession of the claimed genus because the specification does not convey to one of skill in the art a representative

number of variants in structure and function of any such polypeptide that has the claimed/structure and function.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-60 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bolotine et al (FR 2807446, published October 10, 2001; pages 1-87, 120, 183, and 198-217 only).

Bolotine et al teach the entire genome sequence of *Lactococcus lactis*. Bolotine et al also teach the polypeptide open reading frames and corresponding nucleic acids (see Tables 1 and 2. In particular Bolotoine et al teach open reading frame 1806 entitled ysbC at page 183 and it corresponding encoding nucleotide sequence at page 120. The polypeptide sequence is 98.5% identical as compared with the nucleic acid set forth in SEQ ID NO:2 (see attached alignments). The sequence of the prior art is also 100% identical with "an amino acid sequence identical to SEQ ID NO:2", as "an amino acid sequence" in the claims has been interpreted as reading on any subsequence or fragment of SEQ ID NO:2. Bolotine et al teach the nucleic acid comprising a heterologous promoter in conventional plasmids or integrative vectors for the expression of the encoded polypeptide and are contained in a host cell (see the disclosure pages 1-86 and claims 1-110 in particular). The claimed functions are inherent to the nucleic acid and polypeptide

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structure(s). As such, the structure necessarily has the claimed function(s) in the absence of convincing factual evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicant's nucleic acid and protein with the nucleic acid and protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art polypeptide and nucleic acids do not possess the same functional characteristics of the claimed nucleic acid encoding the protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of the Claims

Claims 37-60 stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Shanon Foley can be reached on 571-272-0898.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Patricia A. Duffy, Ph.D.

Primary Examiner

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